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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,604	03/08/2004	Richard S. Bein	355492-2971	1765

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EXAMINER	
SAMALA, JAGADISHWAR RAO	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
07/20/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/796,604	BEIN ET AL.	
	Examiner	Art Unit	
	JAGADISHWAR R. SAMALA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-8,10-16 and 24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4-8, 10-16 & 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicant's Amendments and Request for Continued Examination filed on 06/04/2009.

- Claims 2-3, 9 and 17-23 have been cancelled.
- Claim 24 has been added.
- Claims 1, 4-8, 10-16 and 24 are pending in the instant application.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/04/2009 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1, 4-8, 10-16 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 4-8, 10-16 and 24 are vague and indefinite because it is unclear how the ratio of biocompatible polymer to the water-insoluble biocompatible contrast agent 0.07 or greater can arrive. With biocompatible polymer having lower limit from 2 to 40 percent, it is impossible to arrive the recited ratio of 0.07. Please clarify in order that one may readily ascertain what is being claimed.

Claim 4 is vague and indefinite because claim 1 recites "from greater than 40 to 60 weight percent" of water-insoluble biocompatible contrast agent and claim 4 recites a concentration of from 40 to 55 weight percent. Please clarify in order that one may readily ascertain what is being claimed.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1, 4-8, 10-16 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whalen et al (US 2002/0090339) in view of Paterson et al (US 2004/0224864) or Porter et al (US 2004/0197302).

Whalen discloses a composition comprising: a biocompatible polymer at a concentration of from about 2 to about 50 weight percent; and a biocompatible contrast agent at a concentration of from about 10 to about 40 weight percent; and a biocompatible solvent from about 10 to about 88 weight percent wherein the weight percent of the biocompatible polymer, contrast agent and biocompatible solvent is based on the total weight of the complete composition (abstract and 0032-0035). The preferred biocompatible polymers include cellulose acetates, ethylene vinyl alcohol copolymers and mixtures thereof (0060). The water insoluble contrast agents include tantalum, tantalum oxide, and barium sulfate of particle size of about 10 microns or less and more preferably at from about 1 to about 5 microns (0067 and 0078). The biocompatible solvent includes ethyl lactate, dimethylsulfoxide, ethanol, acetone and the like (see 0069). Additional disclosure includes that sufficient amounts of the contrast agent can be added to the biocompatible solvent to achieve the effective concentration for the complete composition (0077).

Whalen meets the claim limitation but fails to disclose a water-insoluble, biocompatible contrast agent from greater than 40 to 60 weight percent therein.

Patterson discloses a composition comprising biocompatible polymer from about 1 to about 12 weight percent; a biocompatible water-insoluble contrast agent from about 20 to about 55 weight percent and biocompatible solvent (0138, 0193 and 0213). The

ratio of biocompatible polymer to the water-insoluble biocompatible contrast agent is within the broad scope of 0.07 or greater when calculated with the recited amounts.

Porter discloses a composition comprising a solution of about 3 to about 12 weight percent of biocompatible prepolymer, about 20 to about 55 weight percent of water-insoluble biocompatible contrast agents and additional biocompatible solvent added to enhance one or more of the properties of the composition e.g., lubricity (0053 and 0069).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a water-insoluble, biocompatible contrast agent from greater than 40 to 60 weight percent into Whalen's composition. The person of ordinary skill in the art would have been motivated to make those modifications, because composition comprising higher concentration of water-insoluble, biocompatible contrast agent can increase the degree of visualizing effect (Patterson, 0073), capable of being monitored during injection into a mammalian subject and reasonably would have expected success because both Whalen and Patterson's composition is used in the same field of endeavor such as compositions useful in embolizing mammalian blood vessels, to ablate diseased tissue and to treat aneurysms and/or AVMs and Patterson and Porter disclosed using the higher concentration of water-insoluble contrast agents within applicant's range.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Omum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1, 4-8, 10-16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5,667,767and claims 1-8 and 16-23 of U.S. Patent No. 5,695,480. Although the conflicting claims are not identical, they are not patentably distinct from each other because US '767 and '480 claim a composition comprising a polymer, including polyvinylacetate, cellulose acetate butyrate, nitrocellulose, and copolymer of urethane/carbonate and styrene/maleate, a solvent which solubilizes the polymer, including dimethylsulfoxide, an insoluble contrast agent, including tungsten, gold, and platinum, and 0.1-25 % water insoluble radioisotopes.

The instant application claims a composition comprising 2 to 40 % of a biocompatible polymer, including polyvinylacetate, cellulose acetate butyrate, nitrocellulose, copolymers of urethane/carbonate or styrene/maleic acid, biocompatible solvent dimethylsulfoxide, and a biocompatible water-insoluble contrast agent including barium sulfate, tantalum, tantalum oxide, gold, tungsten, or platinum. Embolizing blood vessels is disclosed (page 7 lines 16-17). Thus, the claim is readily envisaged by the teaching of the prior art and the claim is properly included in the rejection.

Conclusion

1. No claims are allowed at this time.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618

Jagadishwar R Samala
Examiner
Art Unit 1618

sjr